



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,488	04/20/2004	Douglas A. Lorenz	PC25825A	4855
28880	7590	01/16/2009		
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 GROTON, CT 06340			EXAMINER COPPINS, JANET L	
			ART UNIT	PAPER NUMBER
			1626	
			NOTIFICATION DATE	DELIVERY MODE
			01/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No. 10/828,488	Applicant(s) LORENZ ET AL.	
	Examiner JANET L. COPPINS	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-12 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 7-12 and 15-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-5, 7-12 and 15-18 are now pending in the instant application.

Response to Amendment

2. Applicants' Amendment and Response, submitted September 17, 2008, has been reviewed by the Examiner. Accordingly, claims 6, 13 and 14 have been cancelled, and claims 1 and 10-12 have been amended.

Previous Claim Rejections –

35 USC § 112

3. Claims 10-14 previously rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In view of Applicants' amendatory changes to the claims, the rejections have been withdrawn.

35 USC § 102

4. Claims 1-3 previously rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/42209 A1, to Pflaum, Zlatko. In view of Applicant's amendment to claim 1, in order to further limit the claim by inserting "spray-drying" into the final step, the anticipation rejection has been withdrawn. However, please see below, regarding a new obviousness rejection over the same reference.

New Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-3 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/42209 as applied to claims 1-3 above, and further in view of the Gaspar et al article.

Applicants are claiming the following process:

Applicants recite a process of forming amorphous atorvastatin, comprising the steps of:

Art Unit: 1626

dissolving atorvastatin in a hydroxylic solvent, and then rapidly evaporating the solvent to form amorphous atorvastatin.

Determining the scope and content of the prior art

The WO document teaches a process of producing amorphous atorvastatin, wherein a crystalline form of atorvastatin is dissolved in a low molecular alcohol (i.e. a hydroxylic solvent) and then the solution is dried by evaporation.

Regarding the “second solvent” present in the solutions of the WO document, Applicants recite that atorvastatin is dissolved in a solution “**comprising** a hydroxylic solvent”. Therefore, the contents of the solution are open-ended and may contain additional solvents, as discussed in the WO document. Regarding claims 2 and 3, please refer specifically to pages 9 and 10, in which several Examples are taught wherein atorvastatin is dissolved in methanol or ethanol and then the solution is evaporated away.

Gaspar et al discuss the technique of spray drying, detailing the many benefits of obtaining products of liquid solutions via the evaporation of the solvent through spray drying. Gaspar et al teach the advantages of spray drying a product solution to obtain an amorphous product, since it is an almost instant transition from liquid to solid phases, with increased yield and bioavailability of the product (please refer to the bottom of page 2).

Ascertaining the difference between the prior art and the claims

The only difference between the prior art and the instant claims is that WO 01/42209 does not specifically discuss spray drying as a means for evaporating the hydroxylic solvent from the solution containing amorphous atorvastatin.

Resolving the level of ordinary skill in the pertinent art

However, given the prior art process as disclosed in WO 01/42209, which teaches each element of instant claims 1-3, except for the technique of spray-drying as an evaporation step, combined with the teachings of the Gaspar et al article, which promotes the advantages of spray drying, it would be have been obvious to combine the teachings of the cited references in order to more efficiently obtain amorphous atorvastatin.

Since both processes were known in the art at the time of filing, one skilled in the art would know to perform the process of forming amorphous atorvastatin, as outlined in WO 01/42209, and to add the highly efficient step of spray drying the hydroxylic solvent away to obtain the amorphous atorvastatin, quickly, and in high yield.

The claimed process is no more than a selective combination of prior art teachings done in a manner obvious to one of ordinary skill in the art since each step of the process appears to be relatively complete in itself and there is no indication of an interaction between steps of such a type that would lead one of ordinary skill in the art to doubt that a substitution of alternative steps known to the art could be made. *In re Mostovych*, 144 USPQ 38 (1964).

The Examiner recommends incorporating some of the latter claims into claims 1-3, in order to distinguish the instant claims from the prior art processes.

Claim Objections

9. Claims 4, 5, 7-12 and 15-18 are objected to as being depending on rejected base claims.

Conclusion

10. In conclusion, claims 1-5, 7-12 and 15-18 are pending, claims 1-3 are rejected, and claims 4, 5, 7-12 and 15-18 are also objected to.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. COPPINS whose telephone number is (571)272-0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/828,488
Art Unit: 1626

Page 7

/REI-TSANG SHIAO /

Janet L. Coppins
January 2, 2009

REI-TSANG SHIAO
Primary Examiner, Art Unit 1626